UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/605,283 | 09/19/2003 | Kapil N. Bhalla | 1372.76.PRC | 2282 |

21901 7590 03/29/2007
SMITH HOPEN, PA
180 PINE AVENUE NORTH
OLDSMAR, FL 34677

| EXAMINER | |
|---|---|
| JAGOE, DONNA A | |
| ART UNIT | PAPER NUMBER |
| 1614 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 03/29/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/605,283 | BHALLA ET AL. | |
| | Examiner | Art Unit | |
| | Donna Jagoe | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *17 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The amendment filed September 21, 2006 has been received and entered.

Claims 1-16 have been canceled and new claims 17 and 18 have been added.

***Claims 17 and 18 are pending in this application.***

Applicants' arguments filed September 21, 2006 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Emelen et al. U.S. Patent Application Publication No. U.S. 2005/0096468 A1 with a Provisional priority date of March 13, 2002 taken with Jolivet et al. U.S. Patent No. 6,645,972 with a Provisional Priority date of November 2, 2001.

Van Emelen et al. teach a combination (page 7, paragraph [0114]) of a Histone Deacetylation inhibitor (HDAC inhibitors) (page 6 paragraph [0084]) with another agent to treat cancer and cause apoptosis of cancer cells (page 6, paragraph [0085]) for *inter alia* leukemias (page 6 paragraph [0086]). Agents such as kinase inhibitors, for example imatinib mesylate are recited (page 8 paragraph [0128]) and HDAC inhibitors such as suberoylanilide hydroxamic acid (SAHA) are recited (Page 1, paragraph [0004] and page 8 paragraph [0149]) and a synergistic effect is achieved (page 9, paragraph

[0159]). It does not teach exposure of the HDAC inhibitor and the tyrosine kinase inhibitor for about 48 hours, however, Van Emelen et al. teach administration of the agents "once, twice or more per course of treatment, which may be repeated, for example every 7, 14, 21 or 28 days. If the agent is administered daily, this would encompass exposure for about 48 hours (page 9, paragraph [0170]). It would have been obvious to employ the HDAC inhibitor and the tyrosine kinase inhibitor for about 48 hours motivated by the teaching of Van Emelen et al. that the HDAC inhibitors along with another chemotherapeutic agent, such as kinase inhibitors, for example imatinib mesylate are recited (page 8 paragraph [0128]) can be administered once, twice or more per course of treatment, which may be repeated, for example every 7, 14, 21 or 28 days. It does not teach the method where the cancer cells are imatinib mesylate refractory. Jolivet et al. teach treatment of acute leukemia is very complex (column 1, line 35) and resistance to agents occurs, particularly in Bcr-Abl tyrosine kinase inhibitor (column 3, lines 25-60) such as imatinib mesylate (column 2, lines 39-51). Van Emelen teach a synergistic effect when another medicinal agent ad HDAC inhibitor are administered simultaneously or sequentially (page 9, paragraph [0159]). It is noted that there are other agents recited for treatment of cancer/leukemia. The claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts. It would have been obvious to one of ordinary skill in art at the time it was made to employ inhibitors of HDAC along with Bcr-Abl tyrosine kinase inhibitors to induce apoptosis in leukemia, as taught by Van Emelen et al. especially where there is

resistance to the Bcr-Abl tyrosine kinase inhibitors, normally employed to treat leukemia and taught by Jolivet et al.

***Response to Arguments***

Applicant asserts that Van Emelen clearly indicates that the administration is to be weekly, not daily. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., daily administration) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claim recites that the composition be contacting the living cells for about 48 hours. It does not recite that the composition be administered daily, or even every 48 hours. The only limitation is that the composition should be in contact with the cells for 48 hours. This can be accomplished by an infusion of the composition, as is usually done in cancer chemotherapy.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe
Patent Examiner
Art Unit 1614

March 21, 2007

3/24/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER